

REMARKS

Claims 19 and 26-28 are pending and stand rejected in the Office Action. Claims 19 and 28 have been amended to more clearly recite the claimed invention. Support for the amendments is found in the specification as originally filed. No new matter has been added.

I. THE REJECTIONS UNDER 35 U.S.C. § 112 SHOULD BE WITHDRAWN

Claim 19 is rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite.

Applicants have amended claim 19 thereby overcoming the rejection. Support for the amendment can be found in the specification at paragraph [0023]. Applicants respectfully request the rejection be withdrawn.

Claim 28 is rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement.

Applicants have amended claim 28 thereby overcoming the rejection. Applicants respectfully request the rejection be withdrawn.

II. THE REJECTIONS UNDER 35 U.S.C. § 103 SHOULD BE WITHDRAWN

Claims 19 and 26-28 are rejected under 35 U.S.C. § 103 as obvious over U.S. Patent No. 6,156,355 to Shields (“Shields”) in view of U.S. Patent No. 6,737,089 to Wadsworth (“Wadsworth”) and Klimberg et al. *Arch Surg.* 1990 (“Klimburg”) and further in view of Taber’s Cyclopedic Medical Dictionary (1997) (“Taber”). Applicants respectfully traverse the rejection for at least the following reasons.

The U.S. Supreme Court analyzed the test for obviousness in *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007). “There is no necessary inconsistency between the [teaching, suggestion, motivation] test and the *Graham* analysis. But a court errs where it transforms general principle into a rigid rule limiting the obviousness inquiry.”

Id. The Supreme Court's analysis in KSR relies on several assumptions about the prior art landscape. First, KSR assumes a starting reference point or points in the art, prior to the time of invention, from which a skilled artisan might identify a problem and pursue potential solutions. Second, KSR presupposes that the record up to the time of invention would give some reasons, available within the knowledge of one of skill in the art, to make particular modifications to achieve the claimed compound. *See Takeda Chemical Industries, LTD et al. v. Alphapharm PTY., Ltd.*, 492 F.3d 1350, 1357 (Fed. Cir. 2007). Third, the Supreme Court's analysis in KSR presumes that the record before the time of invention would supply some reasons for narrowing the prior art universe to a "finite number of identified, predictable solutions," KSR 127 S. Ct. at 1742. In *Ortho-McNeil Pharmaceutical, Inc. v. Mylan Laboratories, Inc.*, 520 F.3d 1358, 1364 (Fed. Cir. 2008), the Federal Circuit further explained that this "easily traversed, small and finite number of alternatives . . . might support an inference of obviousness." However, to the extent an art is unpredictable, as the chemical arts often are, KSR's focus on these "identified, predictable solutions" may present a difficult hurdle because potential solutions are less likely to be genuinely predictable. *See Takeda.*

The claims encompass, *inter alia*, methods for treating diarrhea in a cat suffering from inflammatory bowel disease comprising feeding the cat a diet including ascorbic acid, omega-6 fatty acid(s), crude fat, glutamine, fermentable fiber(s), antioxidant(s), and omega-3 fatty acid(s).

Applicants respectfully submit that the combination of references does not disclose or suggest the claimed invention.

Shield discloses breed-specific dog food formulations that comprise chicken meat as the major ingredient, rice as the predominant (or sole) grain source, fruit and/or vegetable fiber as the primary or sole fiber source, unique fat and antioxidant blend, vitamins, herbs and spices, carotenoids, and no corn or artificial colors, preservatives, flavors or sugars are provided. (*See* Shields at Abstract). The fact that Shields is directed to specialized diets for specific breeds of dogs would teach one of ordinary skill in the art away from modifying the disclosure of Shields to obtain the claimed

methods, which is intended for cats. Indeed, the Examiner relies on Shields disclosure of a “Herding Diet” directed to specific dogs to contrive the obviousness rejection of the claims, which are directed to methods of treating diarrhea in a cat suffering from inflammatory bowel disease.

Wadsworth discloses an animal food product formulated with Morinda Citrifolia, or Noni, from the Indian Mulberry plant. (*See Wadsworth at Abstract*). According to Wadsworth, the addition of Noni to the animal food product of the invention serves to provide significant health advantages not found in prior art animal food products. (*Id.*). One of the additional substances, which can be further included in the compositions is glutamine. (*See Wadsworth at claim 1, “[t]he animal food product of claim 1, further comprising glutamine present in an amount between about 5-10 percent by weight.”*). Thus, this is not a suggestion to achieve the “benefits of glutamine on intestinal health during times of gastrointestinal stress” as alleged by the office action, but merely the Examiner picking glutamine from the ingredients disclosed in Wadsworth to allege a suggestion in the art.

Klimberg discloses that rats treated with abdominal radiation suffered from gastrointestinal disorders including diarrhea. Klimberg does not disclose a pet food composition for treating diarrhea in a cat and is not even relevant to the claimed invention. Taber is merely a medical dictionary that describes diarrhea, but again, there is not disclosure or suggestion of a pet food composition for treating diarrhea in cats.

Applicants respectfully submit that Shields in combination with Wadsworth, Klimberg, and/or Taber does disclose or suggest the claimed methods. In particular, Shields is silent with regard to claimed method of treating diarrhea in a cat suffering from inflammatory bowel disease with the claimed ingredients. Shields is directed to specialized dog foods for specific breeds of dogs. The specialized nature of the pet food compositions disclosed in Shields would teach away from their administration to other breeds of dogs, much less cats suffering from inflammatory bowel disorders. Moreover, one of ordinary skill in the art would not have had a reason to select among

the several unpredictable alternatives (*i.e.*, the various ingredients in the pet food composition) to obtain the claimed invention. *See, e.g., Ortho-McNeil*. Indeed, Shields discloses myriad different ingredients that are to be administered to specific breeds of dogs. One of ordinary skill in the art would not be motivated based on the disclosure of Shields to obtain the claimed compositions for cats suffering from inflammatory bowel disorders.

Applicant's respectfully submit that the Examiner must view the invention as a whole (*i.e.*, methods for treating diarrhea in a cat suffering from inflammatory bowel disease comprising feeding the cat a diet including ascorbic acid, omega-6 fatty acid(s), crude fat, glutamine, fermentable fiber(s), antioxidant(s), and omega-3 fatty acid(s) within the claimed amounts). Casting an invention as a combination of old elements leads improperly to an analysis of the claimed invention by the parts, not by the whole. (*See, e.g., Custom Accessories, Inc. v. Jeffrey-Allan Industries, Inc.*, 807 F.2d 955 (Fed. Cir. 1986)). Moreover, to reach a proper teaching of a process through a combination of references, there must be stated in the references (or shown in the knowledge generally available in the art) an objective motivation to combine the teachings of references, not a hindsight realization in light of the disclosure of the specification being examined. (*See, e.g., In re Fine*, 5 USPQ.2d 1596, 1598 n.1 (Fed Cir 1988)). The teaching or suggestion to combine and the reasonable expectation of success must not be based on the Applicants' disclosure. (*Id.* at 493; *see also* MPEP §2142). Recently, the Supreme Court has held that while the teaching-suggestion-motivation (TSM) test should not be applied rigidly, it still remains necessary to identify a reason that would have prompted a person of ordinary skill in the art to combine elements from the prior art as the new invention does. *KSR v. Teleflex*, 550 U.S. 398 (2007), 127 S. Ct. 1727, 82 U.S.P.Q.2d 1385 (2007). Applicants respectfully submit that the legally required combination of Shields and Wadsworth, Klimberg, and/or Taber fails to meet the tests prescribed by the Supreme Court and the Federal Circuit as discussed below.

Applicants submit that no objective basis was established for combining the teachings of the Shields and Wadsworth, Klimberg, and/or Taber references. Instead,

portions from each reference were taken while ignoring the portions that taught away from the claimed invention. Applicants respectfully submit that Shields is related to breed specific diets for dogs and is silent with regard to compositions and methods for cats, much less the methods encompassed by the claims. There is no reason or suggestion to a person of ordinary skill in the art to modify Shields to obtain the claimed methods recited by claim 1. Indeed, Shields does not suggest using the ingredients recited in the claims in a pet food to obtain the claimed method.

Wadsworth, Klimberg and Taber do not remedy the deficiencies of Shields. None of the cited references is directed to cat food compositions, much less cat food compositions for treating diarrhea in a cat suffering from inflammatory bowel disorders. Therefore, absent a reasonable expectation of success based on the disclosures of Shields and Wadsworth, Klimberg, and/or Taber, the claimed invention relating to methods for treating diarrhea in a cat suffering from inflammatory bowel disease cannot be held obvious in view of the references. *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Finally, Applicants submit that the combination of references would not motivate one of ordinary skill in the art to select the claimed ingredients (e.g., glutamine) from the laundry list of components, much less to randomly pick and choose the claimed ranges of each of the ingredients. Indeed, one of ordinary skill in the art would not read the reference disclosures and be motivated to modify the disclosures to obtain the claimed animal food composition for treating diarrhea in cats from inflammatory bowel disorders. Applicants stress that the Federal Circuit explained that an “easily traversed, small and finite number of alternatives . . . might support an inference of obviousness.” *Ortho-McNeil Pharmaceutical, Inc. v. Mylan Laboratories, Inc.*, 520 F.3d 1358, 1364 (Fed. Cir. 2008). However, these “identified, predictable solutions” may present a difficult hurdle because potential solutions are less likely to be genuinely predictable. *Takeda Chemical Industries, LTD et al. v. Alphapharm PTY, Ltd.*, 492 F.3d 1350 (Fed. Cir. 2007).

Therefore, Applicants respectfully submit that one of ordinary skill in the art would not have been motivated to combine the references to render obvious the claims. Applicants respectfully submit that the rejection of claims 19 and 26-28 under 35 U.S.C. § 103(a) as allegedly obvious should be reconsidered and withdrawn.

Claims 19 and 26-28 are rejected under 35 U.S.C. § 103 as obvious over Chandler (In Practice, 2002) (“Chandler”).

The claims encompass methods for treating diarrhea in a cat suffering from inflammatory bowel disease comprising feeding said cat a diet comprising on a dry weight basis from about 30 to about 50 µg ascorbic acid per gram of pet food composition, about 1.5 % by weight omega-6 fatty acid(s), from about 4 % to about 6 % by weight crude fat, from about 0.1% to about 5% by weight glutamine, from about 0.5% to about 20% by weight fermentable fiber(s), from about 0.1% to about 3% by weight antioxidant(s), and from about 0.1% to about 3% by weight omega-3 fatty acid(s).

Chandler is directed to diets, which include various ingredients, which the Examiner picks and chooses with the impermissible aid of hindsight to obtain the claimed invention. Even assuming *arguendo* that Chandler did disclose each and every ingredient in the claims to treat the claimed disorders in cats suffering from inflammatory bowel disease, there is no suggestion to use the claimed ranges to treat the claimed disorder.

The Examiner contrives the obviousness rejection based on references that disclose a diverse, multitude of ingredients. What the Examiner alleges as a suggestion or motivation in the art to combine or modify the teachings of the references is actually the Examiner picking and choosing from the individual ingredients disclosed in the references. The Examiner’s assertion that it would be obvious to adjust the compounds within the disclosed range is also incorrect. The claims recite specific amounts of ingredients that treat diarrhea in a cat from inflammatory bowel disorders. The general disclosure in the references of amounts of ingredients does not amount to a

teaching or suggestion to modify the reference to obtain the claimed ingredient to treat the claimed disorder.

Therefore, Applicants respectfully submit that one of ordinary skill in the art would not have been motivated to combine the references to render obvious the claims. Applicants respectfully submit that the rejection of claims 19 and 26-28 under 35 U.S.C. § 103(a) as allegedly obvious should be reconsidered and withdrawn.

III. CONCLUSION

For the reasons discussed above, Applicants believe that claims 19 and 26-28 are in an allowable condition and respectfully request an early Notice of Allowance. The Examiner is invited to telephone the undersigned if that would be helpful to resolving any issues.

It is believed no fees are due; however, the commissioner is authorized to charge any fees and credit any overpayments to Deposit Account No. 50-2957.

Respectfully submitted,

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